

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015 (GBW)
)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	
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SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.)	
)	
Plaintiff/Counter-Defendants.)	

**SAREPTA THERAPEUTICS, INC.’S AND UWA’S MOTION TO STAY ANTITRUST
COUNTERCLAIM DEADLINES PENDING RESOLUTION OF SAREPTA
THERAPEUTICS, INC.’S AND UWA’S MOTION TO BIFURCATE AND STAY
(EXPEDITED REQUEST)**

INTRODUCTION

Sarepta Therapeutics, Inc. and the University of Western Australia (collectively, “Sarepta”) respectfully request that the Court enter an order staying all deadlines as to Nippon Shinyaku Co., Ltd. and NS Pharma, Inc.’s (“NS”) antitrust counterclaim Claim XI (D.I. 344 at ¶¶ 93-111) pending this Court’s consideration of Sarepta and UWA’s Motion to Bifurcate and Stay Antitrust Counterclaim (D.I. 345) (“Motion to Bifurcate and Stay”). Absent a limited stay, the Motion to Bifurcate and Stay may become moot due to NS’s decision to serve affirmative expert reports relating to the antitrust case on September 8, 2023, which would require Sarepta and UWA to serve rebuttal reports on October 5, 2023. (D.I. 341)—notwithstanding the fact that discovery has not even begun on the antitrust issues. Because of the rapidly approaching rebuttal report deadline, Sarepta respectfully requests expedited consideration of this motion.

STATEMENT OF FACTS

Fact discovery in this litigation closed on July 27, 2023 (D.I. 269). This Court granted NS’s Motion for Leave to File an Amended Answer and New Counterclaims (D.I. 177) on August 14, 2023. (D.I. 317). Sarepta has therefore had no opportunity to conduct discovery on issues core to its antitrust defenses, including discovery related to whether NS has properly defined an antitrust market, alleged harm to competition, potential competitors to Sarepta and NS, product quality, and alleged fraudulent enforcement. (D.I. 345 at 5-6).

Because conducting the discovery necessary for Sarepta’s antitrust defense would derail the pending trial on the parties’ underlying claims of infringement and invalidity, among other reasons, Sarepta filed a Motion to Bifurcate and Stay NS’s antitrust counterclaims on September 5, 2023. Leading up to the filing of Sarepta’s Motion to Bifurcate and Stay the parties negotiated in good faith on potential options for staying the antitrust claim without motion practice, meeting and conferring three times on August 11, 25, and 30, 2023, but could not reach agreement on terms.

Briefing on Sarepta's Motion to Bifurcate and Stay will be complete by no later than September 26.¹

LEGAL STANDARD

This Court has broad discretionary authority to stay proceedings before it. *See Dentsply Int'l Inc. v. Kerr Mfg. Co.*, 734 F. Supp. 656, 658 (D. Del. 1990). "Courts typically rely on three factors in determining whether a stay is appropriate: (1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party." *Ethicon LLC v. Intuitive Surgical, Inc.*, C.A. No. 17-871-LPS, 2019 WL 1276029, at * 1 (D. Del. Mar. 20, 2019). "Courts may also consider whether the moving party would face undue hardship or inequity in the absence of a stay." *Personalized User Model, L.L.P. v. Google, Inc.*, C.A. No. 09-525-LPS, 2012 WL 5379106, at *1 (D. Del. Oct. 31, 2012).

ARGUMENT

A limited stay pending resolution of the Motion to Stay and Bifurcate is warranted here. Fact discovery in this litigation closed on July 27, 2023 (D.I. 269), and the Court allowed NS's antitrust counterclaims to be added on August 14, 2023. (D.I. 317). Discovery on NS's antitrust counterclaims is plainly not "complete," since "important factual issues remain outstanding." *Vitaworks IP, LLC v. Glanbia Nutritionals (NA), Inc.*, C.A. No. CV 19-2259-GBW, 2023 WL 4532540, at *2 (D. Del. July 13, 2023). NS served the expert report of Dr. Robert Maness on September 8, only three days after Sarepta's Motion to Bifurcate and Stay. Even though the parties have not had any opportunity to conduct any antitrust-specific discovery, Dr. Maness purports to

¹ Sarepta does not intend to take the full allotted period to file its reply brief and respectfully requests that the Court consider the fully-briefed Motion to Bifurcate and Stay on an expedited basis.

opine on issues critical to NS's antitrust claims, including antitrust market definition, supposed anticompetitive effects, and NS's alleged antitrust damages. The dearth of antitrust discovery conducted in this litigation to date is readily apparent from the list of materials relied upon disclosed in Dr. Maness's report: out of more than 19,000 documents produced in this litigation, Dr. Maness cites fewer than 70 documents in total. Moreover, the trial date for NS's antitrust claims is entirely contingent on this Court's resolution of Sarepta's Motion to Bifurcate and Stay.

Sarepta will suffer substantial prejudice if discovery is not stayed. Under the parties' recent stipulation to extend deadlines (D.I. 341), Sarepta's expert's rebuttal to the Maness Report would be due on October 5, a little over a week after completion of briefing on Sarepta's Motion to Bifurcate and Stay. Absent a limited stay of deadlines related to the antitrust case pending the Court's consideration of that motion, Sarepta will be forced to expend resources to prepare an antitrust expert rebuttal report, without the benefit of discovery focused on its antitrust defenses. This result would significantly prejudice Sarepta for two reasons. First, Sarepta's expert may be unfairly limited by the record in this case due to Sarepta's inability to conduct antitrust-focused discovery. Second, preparing and serving a rebuttal expert report will effectively foreclose the relief sought by Sarepta's Motion to Bifurcate and Stay before the Court has a meaningful opportunity to evaluate the motion on the merits.

Conversely, a limited stay of antitrust-related deadlines pending the Court's review of Sarepta's Motion to Bifurcate and Stay will not prejudice NS. A stay does not result in undue prejudice simply because it "may delay resolution of the litigation." *Enhanced Sec. Rsch., LLC v. Cisco Sys., Inc.*, C.A. No. 09-571-JJF, 2010 WL 2573925, at *3 (D. Del. June 25, 2010). Sarepta only seeks a stay with respect to the antitrust counterclaim, so NS will not suffer the "outsized consequences" of delay that parties asserting infringement may experience from the stay of patent

proceedings. *Bataan Licensing LLC v. DentalEZ, Inc.*, C.A. No. 22-CV-238, 2023 WL 143991, at *2 (D. Del. Jan. 10, 2023). Rather, even if NS prevails on its antitrust claim, any harm from delay “can be adequately addressed and remedied through money damages.” *Id.*

CONCLUSION

For the above reasons, Sarepta respectfully requests that the Court exercise its discretion to temporarily stay all deadlines, including expert discovery deadlines, as to the antitrust counterclaim pending consideration of Sarepta’s Motion to Bifurcate and Stay. Should the Court deny Sarepta’s Motion to Bifurcate and Stay, the parties would then meet and confer on a proposed revised schedule for antitrust discovery, including related expert discovery, and additional deadlines as necessary. In light of the upcoming deadline for responsive expert reports, Sarepta respectfully requests expedited consideration of this motion.

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September 14, 2023

RULE 7.1.1 STATEMENT

Pursuant to D. Del. LR 7.1.1, counsel for Sarepta Therapeutics, Inc. and the University of Western Australia (“Sarepta”) met and conferred via telephone multiple times with counsel for Nippon Shinyaku Co. Ltd. and NS Pharma, Inc. (“NS”) on the related Motion to Bifurcate and Stay Antitrust Counterclaim (D.I. 345). Counsel for Sarepta understands from those meet and confers that NS opposes stays of discovery related to the antitrust counterclaim. Counsel for Sarepta also contacted counsel for NS via email the morning of September 14, 2023 to confirm that NS’s opposition to a stay of antitrust discovery also applies to this expedited request for a short-term stay and proposed times to further meet and confer if NS was considering taking a different position with respect to this request. At the time of the filing of this motion, counsel for NS has not responded to the aforementioned communication.

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 14, 2023, upon the following in the manner indicated:

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